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AMP Recommends Clinical Pharmacogenomic Testing Best Practices to Preserve Broad Access and Improve Patient Care

Key recommendations include well established clinical validity and comprehendible test reports for healthcare providers

ROCKVILLE, Md. – Sept. 4, 2019 – The Association for Molecular Pathology (AMP), the premier global, molecular diagnostic professional society, today published a new position statement for pharmacogenomic testing. Based on a recent assessment of the current market landscape, the statement includes a list of criteria for laboratories to follow for these types of tests to ensure responsible use, preserve broad access and improve patient care.

Clinical pharmacogenomic tests are valuable tools that can help healthcare providers determine the optimal medication or treatment for a specific patient. These tests are held to the same standards as all other practices of medicine and supporting clinical validity evidence must be determined before the test is offered to patients. Such evidence may be established and/or demonstrated through peer-reviewed literature, clinical practice guidelines, and/or FDA drug labels. Insurance providers have issued positive coverage determinations based on this same level of supporting clinical evidence.

"Today, we're realizing the full potential of clinical pharmacogenomics in this era of precision medicine. These groundbreaking tests provide substantial benefits to patients when the drug-gene association is supported by strong scientific evidence and the healthcare provider is easily able to determine the actionable prescribing decision," said Jordan Laser, MD, Medical Director of Long Island Jewish Medical Center – Pathology and Laboratory Medicine, and Chair of AMP Professional Relations Committee. "This new position statement on pharmacogenomic testing leverages our community's collective expertise in this rapidly developing field and reflects AMP's ongoing commitment to improving professional practice and patient care."

AMP encourages the use of the gene-drug practice guidelines created by the international Clinical Pharmacogenetics Implementation Consortium (CPIC). The AMP Pharmacogenetics (PGx) Working Group is also working on a series of evidence-based expert consensus opinion recommendations designed to help standardize alleles that should be included in clinical testing for frequently used genotyping assays. Together with organizational representation from CPIC and the College of American Pathologists (CAP), the AMP PGx Working Group has published recommendations for selection and genotyping of *CYP2C19* and *CYP2C9* alleles used in clinical assays. There are two additional expert opinion recommendations in development.

AMP continues to evaluate the evolving landscape of pharmacogenomic testing. As part of this evaluation, a group of AMP leaders determined that clinically meaningful pharmacogenomic tests are poised to improve patient care and professional practice, provided certain conditions are met. The set of conditions include:

- All health-related pharmacogenomic claims must have well-established clinical validity.
- The pharmacogenomic testing provider must comply with the CLIA statute and regulations.
- The pharmacogenomic test report should be comprehendible by healthcare providers and include the interpretation of the findings, the significance of the results, as well as the limitations of the test.
- AMP strongly recommends that patients should not change their treatment plan without first talking to their healthcare provider.

To read the full position statement on pharmacogenomic testing, please visit https://www.amp.org/PGxBestPracticesStatement.

ABOUT AMP

The Association for Molecular Pathology (AMP) was founded in 1995 to provide structure and leadership to the emerging field of molecular diagnostics. AMP's 2,500+ members practice various disciplines of molecular diagnostics, including bioinformatics, infectious diseases, inherited conditions, and oncology. Our members are pathologists, clinical laboratory directors, basic and translational scientists, technologists, and trainees that practice in a variety of settings, including academic and community medical centers, government, and industry. Through the efforts of its Board of Directors, Committees, Working Groups, and Members, AMP is the primary resource for expertise, education, and collaboration in one of the fastest growing fields in healthcare. AMP members influence policy and regulation on the national and international levels, ultimately serving to advance innovation in the field and protect patient access to high quality, appropriate testing. For more information, visit www.amp.org and follow AMP on Twitter: @AMPath.

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